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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/352,570	07/13/1999	MICHAEL E. MENDELSON	00398/506001	2454

7590

02/10/2003

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/10/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/352,570	Applicant(s) MENDELSON, MICHAEL E.	
	Examiner Michael Pak	Art Unit 1646	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 7, 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

R sponse to Am ndment

1. The amendment filed 30 September 2002 (Paper No. 15) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 30 September 2002 (Paper No. 15), have been fully considered but they are not found persuasive.

Claim Objections

4. Claims 9 and 10 is objected to because of the following informalities. Claims 9 and 10 recite terms "ER β ", "MAD2", "GST- ER β " which are acronyms which should be defined with the full term. Each independent claim must define the acronym. Appropriate correction is required.

Specification

5. The amendment filed 30 September 2002 (Paper No. 15) and the amendment to the paper sequence listing are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. Applicant is required to cancel the new matter in the reply to this Office Action.

The amendment to specification on pages 16 and 20 to change the amino acid to nucleic acid because the protein does not have the specific amino acid length would not be recognized by one of skilled in the art. The typographical errors could have occurred anywhere including the position of the amino acid sequence and not necessarily the nucleic acid sequence. Furthermore, the specification does not refer to the specific nucleic acid position in the specification nor its interaction with MAD2.

The paper Sequence Listing amendment to add SEQ ID NO:5-7 is new matter which was not disclosed in the original specification.

Claim Rejections - 35 USC § 112

6. Claims 1-3, 6, and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9 and 10 recite terms "estrogen receptor beta", "mitosis arrest deficient 2", "ER beta", "MAD2", or GST-ER β " which is ambiguous because it is not clear what is the metes and bounds of the terms which has no structural limitations. Applicants argue that identifying the acronym with the name overcomes the rejection. However, the rejection is based upon the lack of structural limitations which makes it unclear what is the metes and bounds of the terms. Claims 2, 3, 6, and 11-12 are dependent on claim claims 1 and 10.

Claim Rejections - 35 USC ' 112, first paragraph

7. Claims 1-3 6, 9-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 9 and 10 recite terms "estrogen receptor beta", "mitosis arrest deficient 2", "ER beta", "MAD2", or GST-ER β " which encompasses a variant protein because no structural limitations is provided. Claims 2, 3, 6, and 11-12 are dependent on claim claims 1 and 10. However, the specification discloses working example of species of MAD2 and ER beta which is the essential feature of the invention. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the disclosure does not have written description for the genus of variants. One skilled in the art cannot envision the sequence of all the variants of proteins encompassed by the claim limitation.

Applicant argue that the functional properties of these polypeptides are clearly described in the specification. However, the terms are not limited by structure and the genus encompassed by the term is unlimited. *Eli Lilly* clearly indicated unreasonable genus limited by terms without structure is not patentable. *Eli Lilly* did not allow generic terms such as mammalian or vertebrate.

8. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The recitation of SEQ ID NO:7 is new matter not disclosed in the specification as originally filed.

Claim Rejections - 35 USC § 102

9. Claims 1, 3 6, 9, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by lafrati et al.(Nature Medicine, 1997).

lafrati et al. teach the method of determining vascular cell proliferation when treated with estradiol which expresses estrogen receptor beta(page 546 and figure 3). The vascular cells inherently expresses the MAD2.

Applicants argue that the examiner must provide some evidence in the prior art that describes the missing elements. It should be noted that terms "estrogen receptor beta" or "MAD2" are not structurally limited and encompass many different compounds not just the species in the working example. lafrati et al. disclose effect on cell division. Furthermore, Elledge (Science, 1998, IDS) teaches that MAD2 are ubiquitous in all cell division.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1646

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
30 January 2003